UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION,	:	MDL 1456
	:	Master File No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: ALL ACTIONS	:	
	:	Judge Patti B. Saris

DECLARATION OF JAMES BREEN IN SUPPORT OF FIRST DATABANK, INC.'S OPPOSITION TO DEFENDANTS' MOTION TO COMPEL AND IN SUPPORT OF ITS COUNTER-MOTION TO LIMIT ALL SUBPOENAS SEEKING ADDITIONAL TESTIMONY

I, James Breen, declare under penalty of perjury:

1. I am the Senior Director of Knowledge-Base Services at First DataBank, Inc. ("FDB"), located at 1111 Bayhill Drive, San Bruno, California.

2. I submit this declaration in support FDB's opposition to defendants' motion to compel and in support of its counter-motion to limit all subpoenas seeking additional testimony. I have personal knowledge of the facts set forth herein, except as otherwise noted. I could and would testify competently to these same facts if called as a witness.

First DataBank: Background and Information

3. Established in 1980, FDB is a publisher of drug information that it disseminates in printed form, over the Internet, and electronically on CD-ROMs and other media. FDB gathers and maintains current information on the majority of drugs approved by U.S. Food and Drug Administration. FDB uses this information in its publications and to provide subscription-based

information services. The majority of the information that FDB collects and publishes is clinical in nature, although FDB also collects and publishes certain drug-pricing information.

4. FDB's publications include a number of industry newsletters and monographs, in either print and/or electronic format, including: the *AHFS Drug Information® Monographs*, providing detailed information about more than 1,100 pharmaceutical products to pharmacists, doctors and other medical professionals; *Evaluations of Drug Interactions*™, detailing interactions of both prescription and over-the-counter medications; *First Tox*™, providing clinicians with information necessary to treat drug overdoses and poisoning; and *Price Probe*™, comparing current drug prices, providing drug price history, and analyzing drug price trends.

5. FDB has invested tens of thousands of hours to develop proprietary databases that it uses for its publications and subscriber services. One of these databases is FDB's *National Drug Data File Plus* ("*NDDF Plus*") that contains information concerning some 80,000 plus national drug codes. FDB populates the fields in this database with information it collects from third parties in accordance with data collection and reporting practices that are disclosed to FDB's subscribers and the public.

6. FDB produces customized data files for subscribers, drawn from information in the *NDDF Plus* database. FDB also offers its subscribers various "drug data modules" that supplement *NDDF Plus* data in various ways, providing for example, drug dosage range information, allergy and interactivity information, and the like. Subscribers include physicians, pharmacists, hospitals, insurers, drug manufacturers, healthcare professionals, and Medicaid and Medicare reimbursement entities (including state reimbursement agencies). FDB also publishes various software programs designed to interact with its databases for use in particular clinical

settings or to allow other software and system designers to incorporate First DataBank's databases into their programs

7. FDB is a small, leanly staffed company. At present FDB has a *total* of 225 employees. Only 12 of these employees work in FDB's Editorial Services Department – the department that gathers, maintains and publishes all drug pricing information. Moreover, only two of these employees, including Ms. Morgan, are trained for and have responsibility for communicating with drug manufacturers on the more complex topics involved with drug pricing data and information.

8. FDB's customers rely on it to provide timely, accurate, up-to-date information about thousands of different prescription and over-the-counter drugs, as well as devices used in conjunction with drug therapy. FDB's business depends on its ability to collect and publish accurate and up-to-date information -- work that, for drug pricing information, requires the input and oversight of two key employees.

Drug Information at Issue in the Current Discovery Demands

9. The process used by FDB to collect data for *NDDF Plus* is described in electronic and printed manuals published by FDB, and in FDB's *PricePoint* and *PriceProbe* publications. FDB's drug price collection and reporting practice and policies are also described on FDB's publicly accessible Web site, located at: http://www.firstdatabank.com. The web description of FDB's practices and FDB's printed manuals have all been provided to the parties in this case.

10. FDB does not create or invent the drug pricing data that appears in its *NDDF Plus* database. The data are collected from third parties according to the disclosed procedures. FDB's editorial policies for collecting and reporting drug data do not vary among manufacturers or among drugs.

11. One of the data fields in the *NDDF Plus* database is the Blue Book Average Wholesale Price ("Blue Book AWP"). FDB provides this number for more than 280,000 pharmaceutical products, based on data provided to FDB by drug manufacturers and national drug wholesalers.

12. In the vast majority of cases, to generate the Blue Book AWP, FDB first obtains directly from drug manufacturers their reported "net wholesale price" for a drug, reflecting the manufacturer's stated price of a drug for purchase by a wholesaler. This is also known as the wholesale acquisition cost ("WAC"). FDB also obtains from the manufacturer its suggested wholesale price ("SWP") for the drug, whenever a manufacture publishes an SWP. FDB then separately obtains from the wholesalers their reported mark-up on the net wholesale price for each drug or manufacturer. FDB then multiplies the manufacturer's net wholesale price by the average mark-up to arrive at the Blue Book AWP.

13. In a few instances, usually involving generic drugs, a manufacturer will not provide FDB with its net wholesale price. In this case, FDB determines from the wholesalers whether they agree to the manufacturer's suggested wholesale price. If so, FDB reports the manufacturer's suggested wholesale price as the Blue Book AWP. FDB also reports the manufacturer's SWP as Blue Book AWP in those instances where the wholesalers indicate that they accept AWP and for those drugs that are not sold through wholesalers.

14. In the unusual circumstance where (a) the wholesalers report they do not accept a manufacturer's SWP for a drug, *and* (b) the manufacturer will not directly provide FDB with its net wholesale price, FDB obtains indirect confirmation of the manufacturer's net wholesale price, such as a statement of the net wholesale price on the letterhead of the manufacturer. FDB

then calculates Blue Book AWP in the usual manner, applying the wholesalers' reported mark-up to the manufacturer's net wholesale price.

15. FDB's practices in generating Blue Book AWP were explained at length and in detail in sworn testimony provided by Ms. Morgan in the Texas case. The previous testimony – which was obtained during a 10-hour deposition – confirms precisely how data is collected from manufacturers and wholesalers, how Blue Book AWP is determined, and FDB's practices in those rare instances when Blue Book AWP is something other than the simple product of a manufacturer's net wholesale price times the average wholesaler's markup. This transcript has been produced to the parties in this action, and a copy is submitted for the Court's reference with the declaration of FDB's attorney Robert J. Hawley.

16. As noted, FDB's practices regarding the publication of Blue Book AWP are also publicly available through its website, which contains the following explanation:

> To determine Blue Book AWP, First DataBank typically identifies the Net Wholesale Price (or, in some cases, the Direct Price) of a product and then surveys the full-line national wholesalers to determine the average mark up applied to the manufacturer's line of products or a specific product. Such surveys may be conducted at the request of our customers or when a change in the marketplace occurs (such as a merger of manufacturers) which might occasion a change in prices. First DataBank does not include regional wholesalers or specialty distributors in its surveys.
>
> First DataBank's Blue Book AWP is not intended to represent the wholesale price suggested by the manufacturer. Instead, First DataBank reports the manufacturer's suggested wholesale prices in a separate data field known as "SWP." Thus, the Blue Book AWP field will be populated with a price determined by the wholesaler survey, even if it is different from the SWP. In some cases, if manufacturers do not sell to wholesalers or if wholesalers agree with the manufacturer's suggested wholesale price, the Blue Book AWP and SWP may be the same.

http://www.firstdatabank.com/customer_support/FAQs/.

17. The Blue Book AWP is generated strictly by this process, based on information provided to FDB by the manufacturers and the wholesalers. FDB exercises no discretion or influence in calculating Blue Book AWP.

18. FDB contracts with thousands of health care professionals and reimbursement entities to provide data consistent with and faithful to its published editorial policies. If FDB were to permit its BlueBook AWP data to be dictated by a manufacturer alone, FDB would be violating its obligation to its subscribers.

The Impact on FDB from External Demands for Ms. Morgan's Time

19. In recent years, FDB has been inundated – and overwhelmed – with demands for information in connection with a numerous legal proceedings around the country involving drug pricing: FDB has received *seven* subpoenas in this litigations alone, as well as dozens of other subpoenas and requests for information in other pending AWP litigations. (These demands are described in greater detail in the declaration of Robert J. Hawley.) And I understand that more such requests will be arriving soon. To respond to these myriad subpoenas and other formal demands for information, we have repeatedly been forced to divert the attention of critical employees and to incur costs (both monetary and otherwise) to hire and train the temporary staff necessary to gather the documents and information demanded.

20. Chief among the FDB employees distracted and burdened by these subpoenas and investigative demands is Patricia Kay Morgan, Manager of Product Knowledge Base Services. Ms. Morgan's direct and substantial involvement is required to locate and produce many of the categories of documents requested in the seven subpoenas that have been served by the various parties in this consolidated action, as well as other subpoenas and formal demands (past and ongoing) directed to FDB. As such, Ms. Morgan is forced continually to take time away from

her daily work obligations to coordinate the search for, collection and review of potentially responsive documents. In addition, Ms. Morgan is frequently commanded to appear to provide deposition testimony. In 2002, for example, Ms. Morgan provided over 12 hours of deposition testimony, in deposition sessions relating to FDB's drug price collection and reporting practices. In this litigation alone, Ms. Morgan has been subpoenaed to testify by three different groups of litigants.

21. When Ms. Morgan is pulled away from daily obligations (either to provide deposition testimony or to coordinate document collection efforts), FDB's ability to provide efficiently high quality information to our customers suffers. Ms. Morgan is responsible for the assignment of priorities to the employees in the department that she manages, and for supervising the editorial staff. In her absence, this core editorial function is severely debilitated.

22. Ms. Morgan is responsible for responding to customer requests for information regarding specific NDCs (National Drug Codes). Because of her years of experience in both the pharmaceutical and data publishing industry, Ms. Morgan is able to sort through customer requests and determine whether the requests relate to NDCs tracked by FDB. These requests may be distributed to the staff in Ms. Morgan's absence, but this results in much wasted effort as they try to locate non-existent products.

23. Ms. Morgan receives approximately 200 e-mails each day, with inquiries from FDB's customers and manufacturers. While Ms. Morgan's lean staff attempts to respond when she is out of the office, a number of the requests from customers require her specific attention, and go unanswered in her absence.

24. Each day FDB receives anywhere from eight to 18 outside reports that need to be reviewed and analyzed before any changes to the data can be made the *NDDF Plus* database.

Among its many products, FDB provides daily database updates to some of its customers, so it is important that changes from incoming reports be made on a daily basis. While staff personnel attempt to complete this review and to integrate any new information when Ms. Morgan is out of the office, certain reports require Ms. Morgan's expert review. Moreover, the review and updating of information is far less efficient when it is delegated to Ms. Morgan's small staff.

25. When generic products are launched, Ms. Morgan's oversight and assistance with the review and integration of the new data is essential. Even more essential is her presence to field calls from manufacturers, customers and reimbursement entities regarding the new drugs. When Ms. Morgan is out of the office during these launches, or is otherwise consumed with a document collection effort, it is materially harder for FDB's Editorial Services department to perform its job effectively and efficiently.

26. The burdens of subpoena compliance are not borne by Ms. Morgan alone, but are shared by key personnel at FDB. Key managers and employees in our Government Services department (the group dealing with Medicare data and government contacts) and in our Marketing, Finance, Customer Service and Information Technologies departments, have all been pulled away from their daily work responsibilities to assist with subpoena compliance work.

The Additional Burden FDB Faces in Responding to Endless Subpoenas and Discovery Demands

27. Not only does FDB have to endure the repeated absence and diversion of its key editorial employee Ms. Morgan, it also must bear other, additional burdens on its small operation. For example, in order to respond to the first subpoena issued to FDB in this consolidated action (because of broad scope of the subpoena and large number of document requests), FDB was forced to enlist the participation of critical employees from its Editorial Services, Government Services, Marketing, Finance, Customer Service and Information

Technologies departments. FDB has also incurred (to date) over $20,000 in unbudgeted administrative costs just to deal with this one subpoena response (*e.g.*, to hire temporary staff and to copy and ship all of the documents, CD-ROMS and cartridges).

28. Since 1998, FDB has incurred unbudgeted administrative costs exceeding $50,000 responding to other, similar third-party subpoenas. FDB has been reimbursed for only a small fraction of these costs.

29. FDB has also borne substantial indirect costs in complying with discovery demands. Each time FDB receives a subpoena or a government investigative demand, we must determine which employees, apart from Ms. Morgan, are necessary participants in the search for the specific documents and testimony requested. Identifying, assembling and coordinating the document collection and review efforts entails numerous meetings, conference calls and follow-up conversations – all which distract employees from their everyday work responsibilities. As the Director who manages the employees most affected by these discovery demands, I have witnessed firsthand the extent to which the requests burden company resources, tax productivity, create inefficiency and lead to customer complaints.

30. Since April, we have been served with six new subpoenas in this case, which largely duplicate the original subpoena from the plaintiffs. We received these subpoenas even as we are scrambling to comply with the original subpoena in this same case – an effort towards which we already have dedicated scores of employee hours, hired a temporary staff worker and involved the contributions of eight different FDB employees. To date, we have produced over 28,000 pages of documents plus thousands of additional pages on electronic media (CD-ROMs and floppy disks) in response to the original subpoena, and our compliance is not yet complete.

(We have also produced thousands of pages of documents and thousands of hours of testimony in response to other cases and investigations.)

31. Continuing to produce voluminous documents and/or to make Ms. Morgan available for new depositions imposes a substantial and unfair burden on our company. I urge the Court to deny the motion to compel and to limit the subpoenas so that FDB may resume its role as publisher of information rather than a litigation support firm.

I declare under penalty of perjury that the foregoing is true and correct.

DATED: August 17, 2004

By _____
James Breen